PTO/SB/08A (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 3

Complete if Known	
Application Number	10/037,791
Filing Date	January 3, 2002
First Named Inventor	Stanley M. Crain
Art Unit	1614
Examiner Name	James H. Reamer
Attorney Docket Number	96700/727

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
JHR	20	US- 4,582,835	4/15/86	Lewis, et al.	
	21	US- 3,879,555	4/22/75	Pachter, et al.	
	22	US- 4,935,428	6/19/90	Lewis, et al.	
	23	US- 5,834,477	11/10/98	Mioduszewski	
JHR	24	US- 4,863,928	9/5/89	Atkinson, et al.	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] -Number[4] - Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature	James H Reamer	Date Considered	9/4/03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	10/037,791
Filing Date	January 3, 2002
First Named Inventor	Stanley M. Crain
Group Art Unit	1614
Examiner Name	James H. Reamer
Attorney Docket Number	96700/727

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
JHR	1	Request for Ex Parte Reexamination of U.S. Patent No. RE 36,547. ✓	
	2	Request for Ex Parte Reexamination of U.S. Patent No. 5,767,125.	
	3	Request for Ex Parte Reexamination of U.S. Patent No. 5,580,876.	
	4	Request for Ex Parte Reexamination of U.S. Patent No. 6,362,194	
	5	Request for Ex Parte Reexamination of U.S. Patent No. 6,096,756.	
	6	Dum and Herz, 1981, "In vivo Receptor Binding of the Opiate Partial Agonist, Buprenorphine, Correlated with its Agonistic and Antagonistic Actions," Br. J. Pharmac. 74:627-633.	
	7	Budd, 1987, "Clinical use of opioid antagonists," Balliere's Clinical Anesthesiology 1(4):993-1011.	
	8	Goodman & Gilman, 1975, The Pharmacological Basis of Therapeutics, 5th Edition, Macmillan, New York, Chapter 15, p. 273.	
	9	Crain & Shen, 1995, Ultra-low concentrations of naloxone selectively antagonize excitatory effects of morphine on sensory neurons, thereby increasing its antinociceptive potency and attenuating tolerance/dependence during chronic co-treatment. Proc. Natl. Acad. Sci. U.S.A. 1995 Nov. 7;92(23):10540-10544.	
JHR	10	Konieczko et al. 1988, "Antagonism of morphine-induced respiratory depression with nalmefene," Br. J. Anaesth. 61:318-323.	

Examiner Signature	James H Reamer	Date Considered	9/4/03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B (10-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 3

Complete if Known	
Application Number	10/037,791
Filing Date	January 3, 2002
First Named Inventor	Stanley M. Crain
Group Art Unit	1614
Examiner Name	James H. Reamer
Attorney Docket Number	96700/727

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
JHR	11	Barsan et al. 1989, "Duration of Antagonistic Effects of Nalmefene and Naloxone in Opiate-induced Sedation for Emergency Department Procedures," J. Emerg. Med. 7(2); 155-161.	
	12	Abu-Elheiga et al. 2001, "Continuous fatty acid oxidation and reduced fat storage in mice lacking Acetyl-coA carboxylase 2," Science 291:2613-16.	
	13	Goodman & Gilman (eds.), 1975, The Pharmacological Basis of Therapeutics, 5th Edition, Macmillan, New York, Chapter 15, "Narcotic Analgesics and Antagonists" (by J.H. Jaffe and W.R. Martin) pages 245-283.	
	14	Budd K., 1985, "The use of the opiate antagonist, naloxone, in the treatment of intractable pain." Neuropeptides. 5(4-6):419-22.	
	15	Attal et al. 1989, "Behavioural evidence for a bidirectional effect of systemic naloxone in a model of experimental neuropathy in the rat." Brain Res. 494(2):276-84.	
	16	Kayser et al. 1981, "Dose-dependent analgesic and hyperalgesic effects of systemic naloxone in arthritic rats." Brain Res. 226(1-2):344-8.	
	17	Kayser et al. 1984, "Further evidence for a bidirectional effect of naloxone on the pain threshold in tolerant and non-tolerant arthritic rats." Neuropeptides. 5(1-3):49-52.	
	18	Malaise & Franchimont, 1987, "Methods of clinical and biological assessment of rheumatoid arthritis." Scand. J. Rheumatol. Suppl. 65:81-4, Review.	
JHR	19	Specification of US Patent No. RE 36,547.	

Examiner Signature	James H Reamer	Date Considered	9/4/03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Express Mail No.: EL 500 575 224 US

LIST OF REFERENCES CITED BY REQUESTER

(Use several sheets if necessary)

ATTY. DOCKET NO.	PATENT
7000-076-999	5,767,125
PATENT OWNER	
Albert Einstein College of Medicine of Yeshiva University	
ISSUE DATE	GROUP
June 16, 1998	

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
HM	AA	4,582,835	4/15/86	Lewis et al.			
HM	AH	4,457,933	7/3/84	Gordon et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO

OTHER REFERENCES (*Including Author, Title, Date, Pertinent Pages, Etc.*)

HM	AB	Schmidt *et al.*, 1985, "Postoperative pain relief with naloxone. Severe respiratory depression and pain after high dose buprenorphine," Anaesthesia 40:583-586
	AC	Pedersen *et al.*, 1985, "Naloxone - a strong analgesic in combination with high dose buprenorphine," Brit. J. Anaesth. 57: 1045-1046
	AD	Bergman *et al.*, 1988, "Low dose naloxone enhances buprenorphine in a tooth pulp antinociceptive assay," Arch. Int. Pharmacodyn. Ther. 291:229-37
	AE	Dum and Herz, 1981, "*In vivo* Receptor Binding of the Opiate Partial Agonist, Buprenorphine, Correlated with its Agonistic and Antagonistic Actions," Br. J. Pharmac. 74:627-633
	AF	Vaccarino *et al.*, 1989, "Analgesia produced by normal doses of opioid antagonists alone and in combination with morphine," Pain 36:103-09
	AG	Levine *et al.*, 1988, "Potentiation of pentazocine analgesia by low-dose naloxone," J. Clin. Invest. 82(5):1574-77
	AI	Goodman & Gilman, 1975, *The Pharmacological Basis of Therapeutics*, 5th Edition, Macmillan, New York, Chapter 15, p. 273
	AJ	Specification of US Patent No. Re 36,547
HM	AK	Crain & Shen, 1995, Ultra-low concentrations of naloxone selectively antagonize excitatory effects of morphine on sensory neurons, thereby increasing its antinociceptive potency and attenuating tolerance/dependence during chronic co-treatment. Proc Natl Acad Sci U S A. 1995 Nov 7;92(23):10540-10544

EXAMINER	James H Kramer	DATE CONSIDERED	7/14/03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with **MPEP 609**; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to owner and requester.